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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------|------------------|
| 10/525,259 | 02/22/2005 | Margaret Sin Ka Wan | 13404US | 5000 |
| 7590 | 12/18/2006 | | EXAMINER | |
| Battelle Memorial Institute 505 King Avenue Columbus, OH 43201-2693 | | | FERNANDEZ, SUSAN EMILY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 12/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------|----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/525,259 | WAN, MARGARET SIN KA |
| | Examiner Susan E. Fernandez | Art Unit 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 September 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 31-34 and 37-48 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-30, 35, 36 and 49-51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/21/06.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

The response filed September 26, 2006, has been received and entered.

Claims 1-51 are pending.

Election/Restrictions

Applicant's election of Group I, claims 1-30, 35, 36, and 49-51, in the reply filed on September 26, 2006, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 31-34 and 37-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Claims 1-30, 35, 36, and 49-51 are examined on the merits to the extent they read on the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 14, 22, 23, 26, 29, and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 14 are indefinite since they recite the trade names "New Skin" and "Eudragit RL100." M.P.E.P. 2173.05(u) indicates that "if the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name."

Claims 22 and 23 are rendered by the recitation "the polymer formulation." The recitation lacks antecedent basis, and it is not clear if "the polymer formulation" refers to the formulation of the biologically compatible polymer present in the liquid recited in lines 2 and 3 of claim 1.

Regarding claims 26 and 49, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 29 is indefinite since it is unclear how the step of the claim (preparing a liquid formulation) relates to the steps of parent claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18, 20-28, 35, 36, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee et al. (WO 98/03267) in view of Shastri et al. (WO 97/16545).

Coffee et al. discloses a method of depositing fibres on a surface wherein a liquid comprising a biocompatible polymer is subjected to an electrohydrodynamic process in the vicinity of said surface (page 4, third paragraph). See Figure 1. Thus, Coffee et al. discloses supplying liquid comprising compatible polymer to a liquid outlet in the vicinity of a surface and subjecting liquid issuing from the outlet to an electric field to cause the liquid to form polymer fibres which are attracted to and deposit onto the surface to form a polymer fibre scaffold, as required by certain limitations in parent claims 1, 14, 16, 18, 20, 21, and 24. Additionally, the reference teaches that the fibres can have a diameter in the range of 10 nm to above 100 microns (page 17, first paragraph, second to last sentence), which meets the diameter limitation of instant claim 7. Further still, the reference teaches that the liquid comprising a biocompatible polymer can be a solution or a melt (page 22, last paragraph) and the polymer can be polylactic acid (polylactide) (page 4, second paragraph) or “New Skin” wherein the fibres formed are approximately 0.5 to 5 microns in diameter (page 19, last paragraph). Thus, limitations in instant claims 10, 22, and 23 are disclosed in the reference. Additionally, the limitations of instant

claims 25, 26, and 49 (wound as the surface) are taught by Coffee et al. (page 4, second paragraph and third paragraph).

Coffee et al. differs from the claimed invention in that it does not expressly disclose that mammalian cells are applied to the Coffee polymer fibre scaffold.

Shastri et al. discloses a method for altering the regeneration, differentiation, or function of cells (claim 1), wherein cells are attached to a surface comprising an electrically conducting polymer (such as a biocompatible polymer, see claim 10). See also the abstract which indicates that conductive polymers are seeded with nerve cells. As indicated at page 15, lines 13-19, the electrically conducting polymer should be porous, where the pores should allow for vascular ingrowth and the seeding of cells without damage to the cells or patient, said pores generally in the range of between approximately 100 and 300 microns. Further still, the Shastri invention can be used to alter the regeneration, differentiation, or function of cells including various “organ cells”, muscles cells, and “cells forming bone and cartilage” (page 18, lines 24-27).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have applied mammalian cells to the fibre scaffold produced by the Coffee methods. One of ordinary skill in the art would have been motivated to do this since the Coffee scaffold comprises of electrically conducting polymer and therefore would have been suitable for cell regeneration and differentiation. In applying mammalian cells either by spraying or seeding (as suggested in Shastri et al.), the applied cells would have inherently grown or elongated preferentially along the fibre of the Coffee fibre scaffold. Thus, claim 1 and its dependants as discussed above (claims 1, 7, 10, 22, 23, 27, 28, and 49) are rendered obvious.

Given that Shastri et al. teaches that the attachment of various types of cells can be used to alter the regeneration, differentiation, or function of cells, it would have been obvious that the regeneration, differentiation, or function of any type of cells, including human adherent cells, human fibroblast cells, and stem cells, would have been altered when applied to the Coffee scaffold. Thus, the cell types recited in claims 11-14 and 16-18 (and the preamble of parent claims 1, 14, 16, 18, 20, 21, and 24) are rendered obvious.

Given the variety of cells that may be applied to the Coffee invention, a wide range of cell sizes would have been applied. Therefore, the diameter of the cells applied could fit within the requirements recited in instant claims 2-6, 8, and 9. Claims 2-6, 8, and 9 are thus rendered obvious.

It is further pointed out that it would have been obvious to a person of ordinary skill in the art to have varied the gap distance between the fibres in the Coffee scaffold to other gap distances, including those recited in the instant claims, through routine experimentation since pores influence the degree of cellular growth. Shastri et al. teaches that pore sizes of about 100 to 300 microns are suitable for their purposes, thus it would have been obvious that gap distances of 100 to 300 microns would have been suitable in the Coffee invention for cellular regeneration, differentiation, and function. Thus, the gap distance limitations in instant claims 15, 18, 20, 21, 24, 35, and 36 are rendered obvious.

In sum, claims 1-18, 20-28, 35, 36, and 49-51 are rendered obvious by the references.

Claims 1-30, 35, 36, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee et al. and Shastri et al. as applied to claims 1-18, 20-28, 35, 36, and 49-51 above, and further in view of Smith et al. (WO 01/27365) and Simpson et al. (WO 02/40242).

As discussed above, Coffee et al. and Shastri et al. render claims 1-18, 20-28, 35, 36, and 49-51 obvious. However, these references do not expressly disclose that the polymer used is polycaprolactone.

Smith et al. discloses that polycaprolactone is a polymer suitable for making fiber wherein a polymer solution in a liquid jet is introduced into an electric field and formed and elongated on a surface, such as a wound (page 11, lines 4-6, page 14, lines 17-20, and page 17, lines 14-20).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have created the fibre scaffold rendered obvious by Coffee et al. and Shastri et al. with a solution comprising polycaprolactone. One of ordinary skill in the art would have been motivated to do this since polycaprolactone is a polymer which can form fibres on a surface when exposed to an electric field and can be used in a wound dressing, as required by Coffee et al. Thus, further limitations of claims 10 and 14, and claim 19 are rendered obvious by the references.

Additionally, Coffee et al. and Shastri et al. differ from the claimed invention in that they do not teach preparing a liquid formulation comprising cell culture medium with a water soluble polymer, or that this liquid formulation is exposed to an electric field to cause the liquid to break into droplets or to form at least one fibre.

Simpson et al. discloses using mixed solutions (nonbiological but biologically compatible material along with substances such as cells) in electroprocessing, wherein fibres or droplets are formed composed of electroprocessed materials as well as one or more substances (page 33, lines 25-28). Electroprocessing is streaming, spraying, sputtering or dripping material across an electric field and toward a target (page 6, lines 37-40).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have introduced mammalian cells by combining a cell culture with a polymer for the formation of fibres by electroprocessing when conducting the invention rendered obvious by Coffee et al. and Shastri et al. One of ordinary skill in the art would have been motivated to do this since this technique is appropriate for delivering cells to an electroprocessed polymer and further would allow formation of fibres as required by Coffee et al. Thus, claims 29 and 30 are rendered obvious.

Note further that Simpson et al. provides further motivation for applying mammalian cells to the Coffee scaffold as Simpson et al. teaches combining cells with an electroprocessed collagen matrix in order to provide scaffolding or seeding for the formation of engineered tissue, where the cells include stems cells and fibroblasts (page 17, lines 19-32 and abstract).

A holding of obviousness is clearly required.

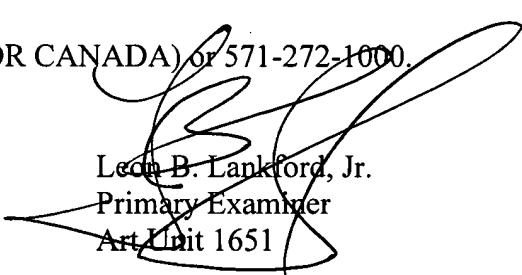
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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